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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/724,105	11/28/2000	Graham P. Allaway	51320-AA/JPW/MAF	6247

7590 12/13/2005

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EXAMINER	
LI, BAO Q	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/724,105	ALLAWAY ET AL.	
	Examiner	Art Unit	
	Bao Qun Li	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This is a response to the amendment filed 10/05/05. Claim 9 has **been** amended. Claims 1-8 and 10-48 have been canceled. Claim 9 is pending before the examiner.

Please note any ground of rejection(s) that has not been repeated is removed. Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Sequence requirements

1. This application contains sequence disclosures **in Fig. 4 and on Table 4 on page 45** that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence **Disclosures.**

2. **Please identify the sequence identification numbers (SE ID NO)** to the disclosed sequences listed above for full compliance with the sequence rules in response to this Office Action. A complete response to this office action should include both compliance with the sequence rules and a response to the Office Action set forth below. Failure to fully comply with **both** these requirements in the time period set forth in this office action will be held non-responsive.

3. Applicants did not comply the sequence rule in response to the above sequence requirement. Applicants are reminded that the requirement is clearly stated in the previous office action, and now is underlined and bolded. Please response accordingly.

Priority

4. Applicant's claim for domestic priority of provision application No. 60/019,941, filed on June 14, 1996 under 35 U.S.C. 119(e) is still denied because the provision application lacks an adequate and enabled description of claim 9 under 35 U.S.C. 112.

5. Applicants argue that enablement disclosure of claim 9 is in light of state of art at the time when the provisional application 60/019,941 was filed; however, it is not persuasive

because the enabling disclosure of the claimed CCR5 antibody in the specification, which has the characterized structure and function as claim drafted is the monoclonal antibody designated as 2D7 (See page 63-66 and Fig. 7) is only disclosed in application 08/874,618, filed on June 13, 1997 rather than the filing date of June 14, 1996 for the alleged provision application No. 06/14, 1996. Therefore, the priority of claim 9 is still considered for the filling date of June 13, 1997 for the record.

Double patenting rejections

6. While applicants traverse the rejections; however, applicants did not point out any error in the rejection. Applicants submit that without conceding the correctness of the Examiner's position, applicants will consider filing a terminal disclaimer if the claim under examination is otherwise allowable.

7. Since claim 9 has been amended to be an anti-CCR5 antibody having a limitations of (1) binding to second loop of CCR5 and inhibiting the fusion of HIV-1 to, and hereby HIV-1 infection of, the CD4+ cell, and (2) blocking binding of a sCD4"gp120 complex to a CCR5 receptor on the surface of such CD4+ cell. The following ODP rejections are still applied based on the full scope of claim 9.

8. Claim 9 is still provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 98-134 of copending Application No. 09,594,983 on the same ground as sated in the previous office action because the scopes of conflict claims are overlapping.

9. Claim 9 still is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10,371,483. Although the conflict claims are not identical, they are not patentably distinct from each other because the claimed monoclonal antibodies in the conflict claims inherently have all structural and biological characteristics as claim 9 amended (See pages 11-13, page 20 and 26 of the specification). Therefore, the species of CCR5 antibody or fragment thereof disclosed in claims 1-5 anticipates the generic antibody and fragment of claim 9

10. The provisional obviousness-type double patenting rejections can be overcome by filling terminal disclaimer as stated in the previous Office Action.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

11. Claim 9 is still rejected under 35 U.S.C. 102(e) as being anticipated by Wu et al. (6,528,625 B1).

12. In response, applicants have amended claim to be an anti-CCR5 antibody or portion thereof capable of (1) binding to second loop of CCR5 and inhibiting the fusion of HIV-1 to, and hereby HIV-1 infection of, the CD4+ cell, and (2) blocking binding of a sCD4:gp120 complex to a CCR5 receptor on the surface of such CD4+ cell. Applicant asserts that there is no teaching in Wu's reference that an anti-CCR5 monoclonal antibodies that blocks binding of a sCD4:gp120 complex to a CCR5 receptor on the surface of a CD4+ cell. Since Wu-2 does not teach the element of the claimed invention, applicants maintain that claim 9, as amended, is not anticipated by Wu-2.

13. Applicants' argument has been fully considered; however, it is not persuasive because Wu et al. clearly teach from lines 19 column 35 to line 21 on column 40 that they have isolated anti-CCR5 monoclonal antibody 2D7 from the 2D7 hybridoma cell line (also referred to as

LS100-2D7-13-1-1-14-14-4 on the behalf of Leukocyte, Inc. (lines 19-29 on column 35), said mAb2D7, interacts with the all chimeric CCR5 that containing second extracellular loop of CCR5 (2EL) and is specificity for the second extracellular loop of CCR5 and (lines 34-35 & 52-53 on column 37); inhibits efficiently the binding of gp120 to the CCR5 L1.2 cells in the presence of soluble CD4 (lines 31-42 on column 39); and inhibits efficiently the binding, entry and fusion of dual-tropic and pseudo M-tropic HIV or dual tropic HIV virus to the target CD4+ and CCR5+ cells as measured by the reporter gene fusion assays (lines 54-67 on column 39, lines 9-22 on column 40, lines 25-62 on column 36 and Figs 11-12), hereby inhibits said viruses infections in the targeted CD4+and CCR5+ cells inherently. Therefore, the claimed invention is anticipated by the cited reference.

14. New ground rejection:

Claim Rejections - 35 USC § 112

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. It is apparent that the monoclonal antibody 2D7 disclosed by the specification is required to practice the claimed invention because only antibody CD7 as disclosed by the entire specification is able to (1) binding to second loop of CCR5 and inhibiting the fusion of HIV-1 to, and hereby HIV-1 infection of, the CD4+ cell, and (2) blocking binding of a sCD4:gp120 complex to a CCR5 receptor on the surface of such CD4+ cell as claim 9 amended. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

17. In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

18. Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

NOTE THE CURRENT ATCC DEPOSITORY ADDRESS

American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209

Applicant is reminded that the following and should amend the specification accordingly. The current address of the ATCC is as follows:

American Type Culture Collection, 10801 University Boulevard, Manassas, VA 20110-2209

If the original deposit is made after the effective filing date of an application for patent, the applicant should promptly submit a verified statement from a person in a position to corroborate the fact, and should state, that the biological material which is deposited is a biological material specifically identified in the application as filed, except if the person is an attorney or agent registered to practice before the Office, in which the case the statement need not be verified. See MPEP 1.804(b).

Conclusion

No claim is allowed.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao Qun Li whose telephone number is 571-272-0904. The examiner can normally be reached on 7:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bao Qun Li
12/01/2005